



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Chung-Hsiun Wu et al. Art Unit : 1632
Serial No. : 10/077,213 Examiner : Anne Marie Sabrina Wehbe
Filed : February 14, 2002
Title : PRODUCTION OF FUSION PROTEINS AND USE FOR IDENTIFYING
BINDING MOLECULES

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

A copy of the reference listed on the attached form PTO-1449 is enclosed. A copy of a communication from a foreign patent office in a counterpart application is also enclosed.

This statement is being filed after a first Office Action on the merits, but before receipt of a final Office Action or a Notice of Allowance. I, the undersigned, hereby certify that each item of information contained in this statement was cited in a communication from a foreign patent office in a counterpart foreign application, the communication being dated July 27, 2004, which is not more than three months prior to the filing of this statement.

No fee is believed due. If, however, a fee is due, please apply any charges (or credits) to Deposit Account No. 06-1050, referencing Attorney Docket No. 13062-002001.

Respectfully submitted,

Date: September 30, 2004

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September 30, 2004
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REPORT

Subject :

The Patent Application No. 91119661 has been examined and it is considered that there is still some ambiguity, as stated in the Explanation Section below, which must be clarified. If the applicant has any concrete counter-evidence or explanation, please file a response and related counter-evidence in duplicate within 30 days from the day after receiving this letter. The response must be filed before the due date. A request for an extension for the deadline CANNOT be made. The Bureau will examine this application only with the presently filed documents if no response is filed by the deadline.

Explanation :

1. It should be in accordance with Articles 48 and 49 of the Patent Law, and Article 28 of Enforcement Rules of the Patent Law if any amendment is made to the application.

2. If a demonstration or presentation to the Bureau is deemed necessary, please make a note "Interview Request" in the response. The place and schedule for the "Interview" will be arranged by the Bureau if the request is considered appropriate (the interview fee is NT\$ 1,000.00).

3. The present application has been examined, and it is considered:

(1) The application entitled "Production of fusion proteins and use for identifying binding molecules" was filed on August 29, 2002. Claims 1-23 are pending where claims 1 and 20 are independent.

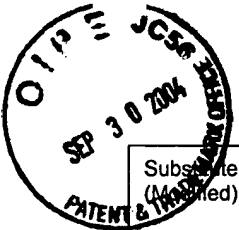
(2) Claims 1-19 direct to a method of isolating a target binding molecule. It is found that Genet. Anal. Tech. Appl. 7:47-52 (published in 1990, here after as Reference 1) discloses a method for purification of specific DNA fragments using a

lac repressor fusion protein. The method is based on a fusion between *lacI* (*E. coli lac repressor gene*, equivalent to the first amino acid sequence of the present application) and *spa* (*Staphylococcal protein A gene*, equivalent to the second amino acid sequence of the present application). The fusion protein, expressed in *E. coli*, is immobilized and purified in a one-step procedure using the specific interaction between protein SPA (equivalent to the first member of the specific binding pair) and the Fc part of IgG (equivalent to the second member of the specific binding pair). The LacI moiety is thereafter used for affinity purification of *lac* operator (*lacO*) containing DNA fragments (equivalent to the target binding molecule of the present application). The difference between Reference 1 and the present application is that the former uses *E. coli* and the later mammals for the expression of fusion proteins. The isolating methods between Reference 1 and the present application are similar. However, expressing specific proteins in mammals to obtain appropriate post-translation modification is well known in the art, as shown in Curr Opin Biotechnol. 2001 Aug; 12(4):411-8 (hereafter as Reference 2). It is considered easily obtainable for those skilled in the art to apply the mammalian expression of Reference 2 to the method for purification of specific DNA fragments of Reference 1. Therefore, claims 1-19 do not meet the requirement of inventive steps and are rejected under Item 4 of Article 22.

(3) Claims 20-32 direct to a method of preparing a purified fusion protein. It is found that Reference 1 discloses a method for purification of specific DNA fragments using a lac repressor fusion protein. The method is based on a fusion between *lacI* (*E. coli lac repressor gene*, equivalent to the first amino acid sequence of the present application) and *spa* (*Staphylococcal protein A gene*, equivalent to the second amino acid sequence of the present application). The fusion protein, expressed in *E. coli*, is immobilized and purified in a one-step procedure using the specific interaction

between protein SPA (equivalent to the first member of the specific binding pair) and the Fc part of IgG (equivalent to the second member of the specific binding pair). The LacI moiety is thereafter used for affinity purification of *lac* operator (*lacO*) containing DNA fragments (equivalent to the target binding molecule of the present application). The difference between Reference 1 and the present application is that the former uses *E. coli* and the later mammals for the expression of fusion proteins. The isolating methods between Reference 1 and the present application are similar. However, expressing specific proteins in mammals to obtain appropriate post-translation modification by is well known in the art, as shown in Curr Opin Biotechnol. 2001 Aug; 12(4):411-8 (hereafter as Reference 2). It is considered easily obtainable for those skilled in the art to apply the mammalian expression of Reference 2 to the method for purification of specific DNA fragments of Reference 1. Therefore, claims 20-32 do not meet the requirement of inventive steps and are rejected under Item 4 of Article 22.

4. Please submit a request of supplement or correction in duplicate with mark (in duplicate) and clean version (in triplicate) of the supplement or correction of the specification or drawings. A full-page specification in triplicate must be submitted if the page number is inconsistent by the supplement or correction of the specification or drawings.



Substitute Form PTO-1449 (Mandatory)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 13062-002001	Application No. 10/077,213
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Chung-Hsiun Wu et al.	
		Filing Date February 14, 2002	Group Art Unit 1632

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AA	Larrick et al., "Producing Proteins in Transgenic Plants and Animals", Current Opinion in Biotechnology 2001, 12:411-418.

Examiner Signature	Date Considered
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EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.